

No. 21-11454-AA

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

EDWIN R. BANKS,
Plaintiff-Appellant,

v.

XAVIER BECERRA,
in his capacity as Secretary of the United States Department of Health and
Human Services,
Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHWESTERN DIVISION
Case No. 5:20-cv-0565-LCB

DEFENDANT-APPELLEE'S RESPONSE TO
MOTION FOR JUDICAL NOTICE

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No. 21-11454-AA

Banks v. Sec'y of HHS

**CERTIFICATE OF INTERESTED PERSONS AND CORPORATE
DISCLOSURE STATEMENT**

The United States Attorney for the Northern District of Alabama, through undersigned counsel, certifies that, in addition to those named in Banks's Motion for Judicial Notice, the following persons may have an interest in the outcome of this appeal:

1. Escalona, Prim F., United States Attorney for the Northern District of Alabama;
2. Daniel Barry, Acting General Counsel, U.S. Department of Health and Human Services;
3. Dana Petti, Chief Counsel, Region IV, Office of General Counsel, U.S. Department of Health and Human Services, Atlanta, GA;
4. Audrey Williams, Assistant Regional Counsel, Region IV, Office of General Counsel, U.S. Department of Health and Human Services, Atlanta, GA; and
5. Paige Coomer, Assistant Regional Counsel, Region IV, Office of General Counsel, U.S. Department of Health and Human Services, Atlanta, GA.

/s/ Don B. Long III
Don B. Long III
Assistant United States Attorney

**DEFENDANT-APPELLEE'S RESPONSE TO
MOTION FOR JUDICIAL NOTICE**

Appellant, Xavier Becerra, in his official capacity as the Secretary of the United States Department of Health and Human Services (“Secretary”), by and through the United States Attorney, submits this response in opposition to Banks’s Motion for Judicial Notice. Banks requests that this Court take judicial notice of a decision rendered by an Administrative Law Judge (ALJ). Banks’s motion should be denied because the ALJ decision is not relevant.

Background Facts

Banks has sought judicial review of the denial of Medicare claims for certain months of a tumor treatment field therapy (“TTFT”) device for treatment of glioblastoma multiforme. Banks received the treatment and was not required to pay for it from his own funds. As discussed in the Secretary’s principal brief, Banks lacks Article III standing because he has suffered no injury-in-fact that is likely to be redressed by a favorable judicial decision. *See Sec’y Br.* at 13.

After all briefs were filed, Banks requested that the Court take judicial notice of a decision rendered by Administrative Law Judge (ALJ) Leslie Holt. Appellant’s Exhibit A. ALJ Holt’s decision concerns coverage of the TTFT device for a different Medicare beneficiary. ALJ Holt upheld the denial of Medicare coverage for the beneficiary’s TTFT device and held the beneficiary liable for the charges. This

decision shows that a beneficiary can be liable to pay for a device in the absence of an advance beneficiary notice, and therefore Banks argues he has standing based on a possible future denial of his claim for the TTFT device. Appellant's Reply Br. at 13.

ALJ Holt's Decision is Not Relevant to the Court's Determination of Whether Banks Has Standing

The Court should deny Banks's motion because ALJ Holt's decision is not relevant to whether Banks has standing to bring this action. "Judicial notice is a means by which adjudicative facts not seriously open to dispute are established as true without the normal requirement of proof by evidence." *Dippin' Dots v. Frosty Bites Distribution*, 369 F.3d 1197, 1204 (11th Cir. 2004) (citing Fed. R. Evid. 201(a) and (b)). "Adjudicative facts are facts that are *relevant* to a determination of the claims presented in a case." *Id.* (emphasis added); see *United States v. Cropper*, 812 Fed. Appx. 927, 931 fn. 3 (11th Cir. 2020) (denying Appellant's judicial notice motion because "the documents at issue would not impact [Appellant's] appeal.").

ALJ Holt's non-precedential and non-binding decision concerning a different beneficiary (and based on a different record) does not affect the resolution of this case. Moreover, Banks's reliance on that decision is based on an incomplete, flawed legal analysis. Specifically, ALJ Holt's decision and the Centers for Medicare & Medicaid Services Manual provision that Banks cites address only the general

protections from billing under 42 U.S.C. § 1395pp. Appellant's Reply Br. at 13.

Neither Section 1395pp nor the manual provision Banks cites control the analysis. Rather, the controlling section is 42 U.S.C. § 1395m(j)(4) which, by incorporating § 1395m(a)(18)(A)(ii), conditions liability of the beneficiary on a written agreement to pay and advance notice of noncoverage. *See* Sec'y Br. at 8 (citing Medicare Claims Processing Manual, Ch. 30, § 30.1, distinguishing between general protection from billing under 42 U.S.C. § 1395pp and 42 U.S.C. § 1395m(j)(4)). Banks also incorrectly contends that section 1395m(j)(4)(C) does not apply to Novocure because it is not a “participating” supplier. *See* Appellant's Reply Br. at 13. Unlike a participating supplier that is required to take assignment of all claims (42 U.S.C. § 1395u(h)) and accept Medicare reimbursement as payment in full (42 C.F.R. § 424.55), Novocure is non-participating, does not furnish services on an assigned basis, and bills the beneficiary, which makes §1395m(j)(4) squarely applicable.

The Seventh Circuit recently considered the same issue in another appeal concerning the denial of coverage for the TTFT device. *Prosser v. Becerra*, ___ F.4th ___, 2021 WL 2621119 (7th Cir. June 25, 2021). In *Prosser*, the court held that Prosser did not have standing to bring her claim for Medicare coverage because she faced no financial liability for the denied claim and any future risk of denial is far

too speculative to establish standing. *Id.* The Seventh Circuit noted that:

Far too many steps lay between the instance coverage denial and any future liability. Novocure would need to require Prosser to sign an advanced beneficiary notice, acknowledging her own financial liability should Medicare deny coverage for the therapy. The company has not done so, and there is nothing in the record to suggest it might do so in the future.

Id.

Conclusion

For the foregoing reasons, ALJ Holt's decision is not relevant to determining whether Banks has standing. Thus, the Court should deny Banks's motion for judicial notice.

Respectfully submitted,

Prim F. Escalona
United States Attorney

/s/ Don B. Long III
Don B. Long III
Assistant United States Attorney

CERTIFICATE OF COMPLIANCE

This appellate brief complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) and Circuit Rule 27 because this brief contains 787 words excluding the parts of the brief exempted by Circuit Rule 27(d)(2).

This motion complies with the typeface and typestyle requirements of Fed R. App. P. 27(d). The brief was prepared in Word 14-point Times New Roman type.

/s/ Don B. Long III
Don B. Long III
Assistant United States Attorney

CERTIFICATE OF SERVICE

I hereby certify that on this the 1st day of July, 2021 the foregoing brief was filed electronically using the Court's CM/ECF system, which will provide notice of the filing to all counsel of record.

/s/ Don B. Long III
Don B. Long III
Assistant United States Attorney